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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,708	09/26/2001	Markus Heil	Le A 34 813	8172

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EXAMINER	
WRIGHT, SONYA N	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,708	HEIL ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☒ Claim(s) *1-6 and 8-11* is/are allowed.

6)☒ Claim(s) *12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response filed August 5, 2003, has been fully considered. The rejections under 102, 103, and 112 and the claim objections in the last Office Action have been overcome with Applicant's amendments.

Upon further consideration, claim 7 has been restricted out because it is classified in a different class than claims 1-6 and 8-12. Claims 1-6 and 8-12 are classified in class 558 and subclass 44+, while claim 7 is classified in class 568 and subclass 716+.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7)Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) Nature of the invention.

Claim 12 is directed to "a method of treating states of neurodegenerative disorders comprising administering to a mammal an effective amount of a compound according to claim 1, wherein said neurodegenerative disorder is cerebral vasospasm, etc. . ." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

2) State of the prior art.

On page 1 of the specification, lines 26-28, Applicant states that WO-A-98/37061, WO-A-00/10967 and WO-A-00/10968 describe certain aryloxyphenyl alkanesulphonates as cannabinoid receptor agonists for the treatment of neurodegenerative disorders. On page 24 of the specification, lines 18-20, Applicant states that permanent focal cerebral ischaemia in the rat is shown in WO-A-98/37061, page 60 et seq.

3) Level of ordinary skill in the art.

There are a vast number of disorders related to autoimmune diseases, metabolic diseases, brain disorders associated with atherosclerotic disease or arterisclerotic

disease, neurodegenerative disorders associated with bacterial and viral infections, etc. . . , and Applicant does not give support for "treating" all forms of these disorders. The level of ordinary skill in the art is high.

4) Level of predictability in the art.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of cannabinoid receptor related diseases, how the cannabinoid receptor is acted upon would affect the possible treatment of any disease.

Hence, in the absence of a showing of correlation between all the diseases claimed as capable of treatment by the instant compound and cannabinoid receptors, one of skill in the art is unable to fully predict possible results from the administration of the instant compound due to the unpredictability of the role of a cannabinoid receptor, i.e. what type of action upon the cannabinoid receptor would be beneficial for the treatment of the diseases.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art

would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

Applicant provides a list of diseases on page 17 of the specification, lines 1-14. However, the various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Applicant does not discuss the differences between the diseases in said list.

5) Amount of direction and guidance provided by the inventor.

The direction present in the instant specification is that the compounds of claim 1 are useful as cannabinoid receptor agonists. However, the specification fails to provide a correlation between the diseases listed and the action of a cannabinoid receptor.

Applicant provides limited guidance regarding the method of treating states of neurodegenerative disorders on pages 17 and 18 of the specification. Applicant provides bioassays on pages 18-24.

6) Existence of working examples.

Applicant provides seven bioassays on pages 18-24. Claim 12 lists a large number of diseases and the bioassays do not enable the full scope of the claim.

7) Breadth of claims.

Claim 12 is extremely broad due to the large number of disorders encompassed by disorders related to autoimmune diseases, metabolic diseases, brain disorders associated with atherosclerotic disease or arterisclerotic disease, neurodegenerative disorders associated with bacterial and viral infections, etc. . . Applicant has not shown evidence that the instant compound is useful in "treating" all of said disorders.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the instant compound for the treatment of neurodegenerative disorders as claimed in claim 12. As a result, one of skill would need to perform an exhaustive search for which disorders can be treated by the instant compound in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which cannabinoid receptor related diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

On page 24, lines 18-20, Applicant states that WO-A-98/37061 gives a model of permanent focal cerebral ischaemia in the rat. Therefore, in order to overcome this rejection, it is suggested that Applicant delete limit claim 12 to the treatment of cerebral ischaemias, and delete all other diseases listed claim 12.

Allowable Subject Matter

Claims 1-6 and 8-11 are allowable over the prior art of record.

The references on the PTO-892 are cited in the 112 rejection, supra.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged

or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

October 5, 2003